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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,441	01/30/2004	Mark L. Lawrence	2343-179-27	6449

24510 7590 12/28/2006
DLA PIPER US LLP
ATTN: PATENT GROUP
1200 NINETEENTH STREET, NW
WASHINGTON, DC 20036

EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/767,441

Applicant(s)

LAWRENCE ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 15-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 15-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/17/04</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-14 and species election SEQ ID NO: 9 and primer pair-SEQ ID NO: 26, 27, in the reply filed on September 29, 2006 is acknowledged. The traversal is on the ground(s) that the species offered is in fact a member of a primer pair. As the primer is used in a primer pair for PCR, Applicants would suggest that a primer pair species be offered for election rather than just a single primer, since the primers are taught in specification to be used in pairs to perform PCR amplification. It is noted that the Examiner agrees and primer pairs SEQ ID NO: 26, 27 will be examined.

The Examiner also acknowledges Applicants request for rejoinder of process claims with an allowable product as required by MPEP 806.05(h).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-39 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 29, 2006.

3. Claims 3-7 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in the recitation of "a nucleic acid molecule". It is not clear what Applicants intend by this phrase. Does Applicant mean the whole nucleic acid sequence set forth in SEQ ID NO: 9, for example, or some portion of SEQ ID NO:

9, as in a fragment? Does Applicant intend for this phrase to mean two nucleic acids of SEQ ID NO: 9? Clarification is requested.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohne et al (Molecular Microbiology, 1996, 20/6:1189-1198), Blais et al (Applied and Environmental Microbiology, Jan. 1997, 63/1:310-313) or Camilli et al (Molecular Microbiology, 1993, 8/1:143-157).

The claims are directed to an isolated virulent gene of *L. monocytogenes*, wherein the gene encodes a protein having virulent biological activity.

Bohne et al, for example, discloses *L. monocytogenes* virulence genes include *prfA*, *plcA*, *hyl*, *mpl*, *plcB* and *actA* (p. 1189). Bohne et al discloses an isolated virulence gene (*prfA* gene) of *L. monocytogenes* (experimental procedures, p. 1196). The prior art anticipates the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' isolated virulence gene (*prfA* gene) of *L. monocytogenes* with the isolated virulence gene (*prfA* gene) of *L. monocytogenes* of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed isolated virulence gene (*prfA* gene) of *L. monocytogenes* and the isolated virulence gene (*prfA* gene) of *L.*

monocytogenes of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunst et al (WO 2002/28891) or Glaser et al (Science, October 26, 2001, 294:849-852).

Glaser et al, for example, discloses isolated virulence gene (*prfA*, *plcA*, *hyl*, *mpl*, *plcB* and *actA* gene) of *L. monocytogenes* (see figure 3; see also attached sequence search report printout).


Kunst et al discloses isolated virulence gene of *L. monocytogenes*. The claimed sequences, SEQ ID NO: 9, 26 and 27 are disclosed (see also attached sequence search report printout). SEQ ID NO: 2909 discloses claimed SEQ ID NO: 26. SEQ ID NO: 2870 discloses claimed SEQ ID NO: 27. SEQ ID NO: 2909 and SEQ ID NO: 2870 disclose claimed SEQ ID NO: 9. Kunst et al also discloses that the sequences are useful as probes and primers for identification and/or detection of *Listeria* contamination. The prior art anticipates the claimed invention.

Since the Patent Office does not have the facilities for examining and comparing applicants' isolated virulence gene of *L. monocytogenes* with the isolated virulence gene of *L. monocytogenes* of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed isolated virulence gene of *L. monocytogenes* and the isolated virulence gene of *L. monocytogenes* of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. No claims are allowed.
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


N. M. Minnifield
Primary Examiner
1645
12/19/06